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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,547	10/15/2001	Kristy Peterson	17162A	3536

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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 07/03/2003

141

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,547

Applicant(s)

PETERSON ET AL

Examiner

LaToya I. Cross

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspond nce address --**
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,4,7-10, 13
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "86" has been used to designate both a plug and film cover. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Also, at page 4, lines 32-33, a step (32) is mentioned. However, there is no step (32) in figure 13. At page 8, lines 23-29, plug (86) is mentioned. However, there is no plug (86) in figure 16.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-47 of copending Application No. 09/977,546. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims do not recite "a separator that permits the first well to be separated from the second well", as is recited in 09/977,546.

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However, the instant claims recite "a first well and a second well". The two wells would obviously require some separator between the two; otherwise, two distinct wells would not exist.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 14, 16-18, 22, 24-26, 28, 29, 31, 33-35, 29-39, 41, 42, 44, 45, 47, 48, 53, 55, 56 and 58-62 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,182,191 to Fan et al.

Fan et al teach a sampling device for collecting transporting and storing a solid or liquid sample. The device includes carrier having two specimen application wells (20) for receiving a specimen sample. The device also include two sample sticks (24) for handling the specimen as recited in claims 1, 17, 18, 28, 41, 42 and 56. A front cover (10) covers both the sample wells and the sample sticks, as recited in claims 3, 22, 31, 33, 44, 45, 58, and 59. Indicia for documenting the patient's information is disposed on the front cover of the carrier shown in figures 1 and 5, as recited in claims 14, 24, 34, 47 and 60. At col. 9, lines 31-46, Fan et al teach that the device may be made from plastic material, as recited in claims 16, 26, 39, and 53. With respect to the shape of the device, as recited in claims 25, 35, 48 and 61, Fan et al show a

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rectangular shaped device in figures 1-4. With respect to the location of the sample handling tools (sample sticks), figures 4-6 show the sample sticks removably attached to the device.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b) in view of the teachings of Fan et al.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 5-13, 19, 20, 36-38, 50-52, 63, 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan et al in view of US patent 3,653,389 to Shannon.

The disclosure of Fan et al is described above. Fan fails to teach sample handling tools having a pair of cooperating arms attached to one another.

Shannon teaches disposable forceps which are manufactured of plastic material, as recited in claim 63. The forceps of Shannon have cooperating arms (1), which are connected to one another by a connecting section (2). The connection section forms a projection, as recited

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in claims 9 and 64. The connection section is equivalent to Applicants' claimed rear portion and the teeth (6) of the forceps of Shannon are equivalent to Applicants' claimed tip portion, as recited in claims 6, 19, 37 and 51. The forceps of Shannon have a bowed (arcuate) section 4 and another bowed section near the teeth of the device, as recited in claims 10, 12, 20, 38, 52 and 63. The tip end of the forceps has a spiked portion and a flat portion, as recited in claim 8. Shannon teaches that forceps having this structure may be easily and cheaply manufactured. They provide the user with a good grip and also are well suitable for engaging objects conventionally used in hospitals and clinics.

It would have been obvious to one of ordinary skill in the art to use the forceps of Shannon in the sample collection device of Fan et al to provide the user with a device more suitable for grasping small samples tightly and a device that is more comfortable to use.

9. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fan et al in view of US Patent 5,593,851 to Jackson.

Fan et al does not provide a sample handling device having a fork at its end.

Jackson teaches a kit for collecting tissue samples. The kit includes a means for handling the tissue sample (36) having a forked end (42). Jackson teaches that the forked end of the specimen handling device allows the sample to be controllably moved with the collection device, without piercing the sample. It would have been obvious to one of ordinary skill in the art to use a forked sample handling device in the collection device of Fan et al to provide the user with a device to better handle the sample without destroying it.

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10. Claims 2, 4, 21, 23, 30, 32, 43, 46, 49 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan et al in view of US Patent 5,955,032 to Kelly et al.

Fan et al does not provide for a "plug" for partially sealing a chamber/well in the device. Fan et al does teach that collection cup may be attached to the device for holding larger volumes of sample.

Kelly et al teach a collection container having a stopper-like closure (160). The closure provides a cover for the sample contained within the collection container, to ensure that the sample is not contaminated or accidentally lost. It would have been obvious to one of ordinary skill in the art to include a plug/stopper on the collection cup of Fan et al to ensure safe keeping of the sample until time for use.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC

June 29, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700